

PSJ15 Exh 82

Message

From: Tetzlaff, Gail S [/O=THCG/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=GAIL.TETZLAFF]
Sent: 4/22/2013 3:51:55 PM
To: Buist, Jennifer M [/O=THCG/OU=Hazelwood01/cn=Recipients/cn=jennifer.walz]; Dunehew, Ryan R [/O=THCG/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Dunehew, Ryan R22f]
CC: Romer, Peter M [/O=THCG/OU=First Administrative Group/cn=Recipients/cn=peter.romer]; Spaulding, Eileen L. [/O=THCG/OU=Hazelwood01/cn=Recipients/cn=eileen.spaulding]
Subject: RE: ANDA order 70272848 for MORPHINE SULFATE ER 15MG TABS on U2 hold

I approve release of the U2 hold on ANDA order 70272848.

Gail Tetzlaff
Director of Government Reporting Compliance
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From: Buist, Jennifer M
Sent: Monday, April 22, 2013 10:36 AM
To: Dunehew, Ryan R; Tetzlaff, Gail S
Cc: Romer, Peter M; Spaulding, Eileen L.
Subject: RE: ANDA order 70272848 for MORPHINE SULFATE ER 15MG TABS on U2 hold

Ryan,

The concern lies with the MTD total. We have seen an increase in various Morphine ER SKUs. If the market is experiencing disruptions, this is the information we require. I will recommend release.

Gail – recommending release of ANDA order 70272848 for MORPHINE SULFATE ER 15MG TABS on U2 hold.

Thanks,

Jen

From: Dunehew, Ryan R
Sent: Monday, April 22, 2013 10:30 AM
To: Buist, Jennifer M
Cc: Romer, Peter M
Subject: FW: ANDA order 70272848 for MORPHINE SULFATE ER 15MG TABS on U2 hold

Jen,

I spoke with Pete today about the current U2 hold on Anda for their 24 bottle order on Morphine ER 15mg (SKU 831501). Market disruptions have occurred across the Morphine ER family in the market and we are not concerned with the Anda order below of 24 bottles. Please release as customers are having to go many places to fulfill their needs.

Please let me know if there is any additional information you would like me to provide. Thanks as always for your time.

Ryan

From: Romer, Peter M
Sent: Monday, April 22, 2013 9:44 AM
To: Dunehew, Ryan R
Subject: FW: ANDA order 70272848 for MORPHINE SULFATE ER 15MG TABS on U2 hold

From: Buist, Jennifer M
Sent: Monday, April 22, 2013 9:34 AM
To: Romer, Peter M
Cc: Tetzlaff, Gail S; Spaulding, Eileen L.
Subject: ANDA order 70272848 for MORPHINE SULFATE ER 15MG TABS on U2 hold

Pete,

We have ANDA order 70272848 for MORPHINE SULFATE ER 15MG TABS on U2 hold. Their quantity ordered exceeds any total quantity for any customer in their segment for the last 18 months. Please see below for verbiage you can send to the customer if need be.

Thank you,

Jen

Order Number	Bill To Customer	Bill To Customer Name	Ship To Customer	Ship To Customer Name	Item Number	Item Description
70272848	50001331	ANDA GENERICS, WESTON, FL	52000095	ANDA INC, WESTON, FL	831501	MORPHINE SULFATE ER

Dear XXX,

As a manufacturer of controlled substances, Mallinckrodt is required by the Drug Enforcement Administration regulations to monitor orders of controlled substances as part of its Anti-Diversion Program.

Our Anti-Diversion Program has identified the order listed below for additional review. Please provide additional information about the circumstances that led to this order. For example, if you recently have experienced a significant increase in your customer base or if another manufacturer of this product is experiencing difficulty supplying this product, provide details about those circumstances.

Customer Order #	NDC	Item	Quantity
261332	0406-8315-01	MORPHINE SULFATE ER 15MG TABS	24.000

Jen Buist (Walz)

Senior Data Analyst – Controlled Substances Compliance
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